

K110119

JUN 10 2011

**Attachment B**  
**510(k) Summary of Safety and Effectiveness**

**Applicant:**

NeoForce Group Inc  
35 Commerce Drive  
Ivyland, Pa 18974  
Registration Number: 3005599562

**Contact Person:**

Monica Ferrante  
VP Regulatory  
Ph 215-672-6800  
Fax 215-672-1123

**Device trade/proprietary name:**

NF-009 Pressure Manometer

**Device common/usual/classification name:**

Airway Pressure Monitor

**Classification:**

Anesthesiology  
21 CFR 868.2600  
Airway Pressure Monitor, CAP, Class II

**Performance Standards:**

None applicable

**Predicate Device:**

Pre-Amendment Pressure Manometer Anesthesia Associates Inc.  
K954486 Mercury Medical Disposable Color Coded Manometer  
K040991 Ambu Inc. Disposable Pressure Manometer  
K072021 NeoPIP Infant Resuscitation Device  
K092085 Ispira Resuscitation System  
K102649 NeoPIP Infant Resuscitator with Flow meter

**Device Description**

The NF-009 Pressure Manometer is a low pressure gauge with a range of -20 to 80 cmH<sub>2</sub>O in marked increments of 1 cm H<sub>2</sub>O. The gauge has color coding green, yellow and red. The Manometer provides visual indication of airway pressure during ventilation or resuscitation.

#### Intended Use

The Pressure Manometer is used to provide visual indication of patient's airway pressure during ventilation. It may be attached by flexible tubing to devices providing expiratory pressure such as resuscitation bags, hyperinflation bags, CPAP Masks or Circuits.

#### Performance Data

The NF-009 Pressure Manometer performs equivalently to the test devices and is within the accuracy information specified for the predicate devices over the operational range. The accuracy for the predicate devices is shown in the comparison table with the worst case values  $\pm 3$  cm H<sub>2</sub>O for measurements less than 15 cm H<sub>2</sub>O and  $\pm 5$  cm H<sub>2</sub>O greater than 15 cm H<sub>2</sub>O. The NF-009 is within 1 cm H<sub>2</sub>O of the Reference Gauge and the Digital Gauge.

The Performance Data demonstrate equivalence to the predicated devices.

#### Substantial Equivalence

The NF-009 Pressure Manometer is believed to be substantially equivalent to currently marketed pressure manometer devices with regards to intended use, safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room –WO66-G609  
Silver Spring, MD 20993-0002

Ms. Monica Ferrante  
VP Regulatory  
NeoForce Group, Incorporated  
35 Commerce Drive  
Ivyland, Pennsylvania 18974

JUN 10 2011

Re: K110119  
Trade/Device Name: Pressure Manometer  
Regulation Number: 21 CFR 868.2600  
Regulation Name: Airway Pressure Monitor  
Regulatory Class: II  
Product Code: CAP  
Dated: May 23, 2011  
Received: May 23, 2011

Dear Ms. Ferrante:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

 for

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

### Indication for Use Statement

510(k) Number:

Device Name: Pressure Manometer

Indications for Use:

The Pressure Manometer is used to provide visual indication of patient's airway pressure during ventilation. It may be attached by flexible tubing to devices providing expiratory pressure such as resuscitation bags, hyperinflation bags, CPAP Masks or Circuits.

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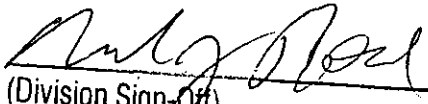
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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  
(Per 21 CFR 801.109)

X

OR

Over-the-Counter Use

  
(Division Sign-Off)

(Optional Format 1/2/96)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

510(k) Number: K110119